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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,918	11/24/2003	Amon Nagler	85189-5500	9844
28765	7590	08/18/2004	EXAMINER	
WINSTON & STRAWN PATENT DEPARTMENT 1400 L STREET, N.W. WASHINGTON, DC 20005-3502			HENLEY III, RAYMOND J	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 08/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/723,918

Applicant(s)

NAGLER ET AL.

Examiner

Raymond J Henley III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/24/2003.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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CLAIMS 1-14 ARE PRESENTED FOR EXAMINATION

Applicants' Information Disclosure Statement filed November 24, 2003 has been received and entered into the application. As reflected by the attached, completed copy of form PTO-1449, the cited reference has been considered.

The references cited by the Examiner on the attached form PTO-892 and not relied upon herein are included to show the general state of the art.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for attenuating the progression of renal fibrosis to end-stage renal failure, does not reasonably provide enablement for preventing renal fibrosis from progressing to end-stage renal failure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The present specification is evaluated by the Examiner as directed by the Court in *In re Marzocchi et al.*, 169 USPQ 367 (CCPA 1971):

"Specification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be

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proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling.” (emphasis added).

Here, the objective truth of the statement that renal fibrosis can be prevented from progressing to end-stage renal failure is doubted in light of applicants’ specification at pages 2-3 where it is set forth that:

“The progression of chronic renal failure (CRF) represents *one of the most challenging problems in nephrology*, as it leads to a large number of patients reaching end-stage renal failure requiring long-term dialysis treatment. Many renal diseases progress to end-stage renal failure with glomerular sclerosis and/or medullar fibrosis, independent of the initial pathogenic mechanism. This suggests that various progressive renal diseases *may* exhibit a common destructive pathway that leads to focal and eventually diffuse glomerulosclerosis and chronic tubulointerstitial disease. Since there is *a possibility* that direct inhibition of renal fibrosis, considered as the final common pathway, will attenuate the development of chronic renal failure (CRF), therapeutic antifibrotic strategies should be targeted to reduce or eliminate this process.” (emphasis added).

Further, nothing in the Examples in the present specification, i.e., Examples 1 and 2, show anything that provide a reasonable basis for concluding that renal fibrosis itself could be prevented, much less prevented from progressing to end-stage renal failure.

The term “prevention” or “preventing” is synonymous with the term “curing” and both circumscribe methods of treatment having absolute success. Since absolute success is not reasonably possible with most diseases/disorders, especially those having etiologies and pathophysiological manifestations as complex or not fully understood as end-stage renal failure, the specification, which is couched in terms that prevention is only possible and further lacks an objective showing that renal fibrosis may actually be prevented from progressing to end-stage renal failure, is viewed as lacking an adequate written description of the same such that the skilled artisan would be enabled to do what applicants are claiming.

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It is suggested that claim 9 be amended to recite, in-part, "A method for attenuating the progression of renal fibrosis to end-stage renal failure comprising..." in order to overcome this rejection.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Pines et al. (U.S. Patent No. 5,449,678).

Pines et al. teach pharmaceutical compositions comprising the claim designated quinazoline compounds, including halfuginone, and a pharmaceutically acceptable carrier as well as methods of preparing such compositions which comprise combining the quinazoline compound with the pharmaceutically acceptable carrier (col. 2, line 52 – col. 3, line 4 and col. 6, lines 16-35). Dosage forms include capsules, tablets, powders, granules or suspensions or solutions in water or non-aqueous media (col. 6, line 49 – col. 7, line 3). It is further taught that such compositions may be administered to a subject in order to treat a variety of fibrotic conditions including those of the kidney (col. 4, lines 20 and 43 and col. 5, line 64) which may be caused an autoimmune disease (col. 4, lines 20 and 43 and col. 5, line 64).

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 7, 8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pines et al., as above.

The differences between the above and the claimed subject matter lie in that Pines et al. fail to highlight:

- (1) a sachet dosage form; and
- (2) the renal fibrosis condition being primary or caused by hypertension or diabetic complications.

However, to the skilled artisan, the claimed subject matter would have been obvious because:

- (1) Sachet dosage forms were well known to be packets containing pharmaceutical powders. The skilled artisan would have been motivated to select such a dosage form because, as noted above, Pines et al. teach powders and the artisan would have appreciated to necessity to package such powders in a manner to facilitate administration to a patient.

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(2) Pines et al. teach methods for treating fibrotic conditions in general (claim 1 at col. 22, lines 46+) which would include fibrotic conditions of the various organs, including the kidney. While fibrotic conditions associated with autoimmune disorders are exemplified, the reference is relevant for all that it teaches and is not limited to the preferred embodiments. Given the broad teaching that fibrotic conditions may be treated and the exemplified renal fibrotic conditions, the skilled artisan would have been imbued with at least a reasonable expectation that fibrotic conditions of the kidney other than those exemplified could also be successfully treated. Absolute predictability is not the standard. In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976).

Claims 9-11 are not subject to the above rejections based on Pines et al. because as explained above under the §112, first paragraph rejection, the claimed method of prevention would not be expected to be possible and it thus believed that Pines et al. fails to teach such prevention in an implicit manner (which would not be the case for an attenuation method).


Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J Henley III
Primary Examiner
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August 17, 2004